REMARKS

The Office action dated November 28, 2008 is acknowledged. Claims 1-38 are pending in the instant application. According to the Office action, claims 1-5 and 25-37 have been rejected and claims 16-24 and 38 have been withdrawn. Claims 1, 2, 5, 8, 12, 14 and 26 have been amended and claims 39 and 40 have been added to more clearly define the present invention, support for which may be found throughout the specification. Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

Election/Restriction

The Applicants thank the Examiner for concluding that the previously submitted arguments against the restriction requirement were persuasive. However, the Examiner has now determined that the claims do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same corresponding technical feature. In particular, the Examiner believes that there is no special technical feature since claims 6 and 10 of U.S. Patent No. 6,599,511 (Asmussen, et al.) teach the instantly claimed reservoir layered oral transdermal pharmaceutical preparation comprising the instantly claimed active desoxypeganine and since the administration composition is further taught as comprising film-shaped (i.e., membrane) semi-permeable release layers. In turn, the Examiner has withdrawn claims 16-24 and 38 as being drawn to a non-elected invention, there being no allowable generic or linking claim.

The Applicants object to the instant restriction requirement, *with traverse*, for the reasons set forth in response to the initial restriction requirement which cited Asmussen,

et al. '510. The arguments therein are incorporated herein in their entirety. The Applicants further submit that the claims of Groups I and II are so linked by a general inventive concept and have corresponding technical features. Asmussen, et al. '511 is directed to a transdermal therapeutic system (TTS) (such as in claim 10) so that the oral, film shaped medicament pursuant to present claim 16 of the with specified dosage amounts and application intervals was not taught or disclosed by Asmussen, et al. '510. The Applicants respectfully object to the instant restriction requirement, with traverse and withdrawal of this objection is therefore respectfully requested.

Specification

The Examiner has objected to the Abstract for not being between 50 and 150 words. An amended Abstract is provided above. Withdrawal of this objection is requested.

Rejection of Claim 1-15 and 25-27 under 35 U.S.C. 112, first and/or second paragraph

Claim 14 has been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner concludes that claim 14 is drawn to a limitation of the composition of claim 1, wherein said composition "additionally contains at least one further pharmaceutically active substance which is not selected from the group consisting of deoxypeganine, deoxypeganine derivatives and salts of deoxypeganine and deoxypeganine derivatives."

Claim 14 is amended herewith in that the further medical substance contained in the medicaments is selected from the group consisting of acetylcholinesterase inhibitors

and opiate antagonist. Support for this amendment may be found in the specification, such as at paragraphs [000016] and [000017]. Withdrawal of this rejection is requested.

Claims 1-15 and 25-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. In particular, the Examiner concludes that the limitation "at least one of the active substance deoxypeganine and a deoxypeganine derivative" of claim 1 renders the claim indefinite. Claim 1 has been amended to clarify the term by the incorporation of Markush Group language. Claim 2 has also been amended accordingly. Withdrawal of this rejection is requested.

Claim 6 has been rejected since there is insufficient antecedent basis for the term "the content of said at least one active substance..." The Applicants respectfully disagree with this rejection. It is submitted that when a medicament contains an active substance, it inherently has a "content" of the active substance. Withdrawal of this rejection is requested.

The Examiner concluded that claims 12 and 37 are indefinite due to the recitation of the medicament having either a "depot effect" or "releasing" said active substance over a period of time. Claim 12 has been amended to delete the term "depot effect." Therefore, withdrawal of this rejection is requested. In turn, it is submitted that the rejection of claim 37, which is dependent from claim 12, is rendered moot in view of the amendment to claim 12.

Claims 5 and 8 have been rejected as being indefinite for the inclusion of a broader limitation together with a narrow limitation within the same claim. Claims 5 and

8 have been amended accordingly, and claims 39 and 40 have been added to respectively depend from claims 5 and 8. Withdrawal of this rejection is requested.

Rejection of Claims 1-15 and 25-37 under 35 U.S.C. 103(a)

Claims 1-3, 5, 14, 25 and 26 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2007/0190117 (Asmussen, et al.) in combination with U.S. Patent No. 6,599,511 (Asmussen, et al.). The Examiner argues that '117 teaches a film-shaped medicament for buccal administration of galanthanmine and at least one further pharmaceutically active substance, which is preferably selected from the group comprising acetylcholinesterase inhibitors (Abstract and claim 10), as well as that the film-shaped medicament has a bilayer or multilayer structure wherein at least one of the layers contains the active substance. However, the Examiner acknowledges that '117 does not further teach any specific examples of acetylcholinesterase inhibitors which may be incorporated into the film-shaped dosage form.

The Examiner refers to '511 for expressly teaching the use of the compound desoxypeganine (1,2,3,9-tetrahydropyrrolo[2,1-b] quinazoline; deoxypeganine) which is a noted inhibitor of acetylcholinesterase in orally, transdermally or sublingually administered pharmaceutical preparations. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to prepare a buccally-administrable, film-shaped dosage form comprising an acetylcholinesterase inhibitor such as deoxypeganine and/or its hydrochloride salt, and at least one other non-deoxypeganine-based active compound such as galanthamine.

Claims 4, 6-13, 15 and 27-37 have been rejected as being unpatentable over the combination of Asmussen, et al. '117 and Asmussen, et al. '511. The Examiner argues that '117 teaches the limitations of these claims, with the exception of teaching that the acetylcholinesterase inhibitor active compounds contribute to these percentages, or if they do, it is not expressly taught how much is attributed to said inhibitors.

The Examiner refers to '511 for expressly teaching the multilayered dosage form as comprising a preferred percent weight range of 5-20% by weight of the desoxypeganine-based active substance.

The Examiner also states that '117 fails to teach the percent weight ranges of desoxypeganine-based active substance either within the reservoir layer or the overall medicament. However, the Examiner concludes that since the values and formats of each parameter with respect to the claimed composition are adjustable, it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to prepare a film-shaped dosage form comprising a deoxypeganine-based active substance at least one other active substance such as galanthamine and format the structure of the dosage form to produce the instantly claimed invention.

The Applicants respectfully submit that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references

when combined) must teach or suggest all of the claim limitation. The Applicants respectfully submit that one skilled in the art would have no suggestion or motivation to combine the aforementioned references in order to arrive at the present invention. Additionally, even if one skilled in the art were to consider the combined teachings of the prior art, each and every limitation of the present invention would not be disclosed, nor would there be a reasonable expectation of success if the aforementioned references were to be considered.

The Applicants respectfully disagree with the Examiner's conclusion set forth in the Office action. It is noted that claim 1 has been amended to recite that the medicament comprises a slow and a fast dissolving layer, both of which contain active substances. The amendment is supported in the specification, such as at paragraph [000033].

The '117 reference teaches a rapidly disintegrating film-shaped medicament for buccal administration of galanthamine or its derivatives or salts, wherein the medicament comprises at least one layer containing the active substance. However, '117 fails to disclose or suggest the use of any other active substance other than galanthamine or its derivatives. Therefore, '117 fails to teach or disclose the use of deoxypeganine in a medicament as well as a medicament with a rapidly and a slowly disintegrating active substance containing layer in accordance with the presently claimed invention.

On the other hand, '511 teaches the controlled and continuous application, preferably in a transdermal therapeutic composition, of deoxypeganine for the treatment of drug addition or dependence. However, '511 fails to teach a medicament having a fast and a slow disintegrating layer as claimed in the present invention, for providing a rapid

onset of the medicament and to maintain an effective level afterward. Specifically, the indicated preference of a dosage form with a delayed release would clearly teach away from the presently claimed invention.

In view of the above, it is submitted that one skilled in the art would not have combined the teachings of the prior art to arrive at the present invention, which is directed to a medicament having two active substance-containing layers of which one is a fast disintegrating layer and the other a slow disintegrating layer to provide an initial dose and a maintenance dose.

It is therefore respectfully submitted that the present invention defined in the present claims is patentably distinguishable over the combination of prior art teachings under 35 U.S.C. 103(a). Based on the aforementioned differences, each and every element of the present invention recited in the present claims are not set forth in the prior art. Moreover, one skilled in the art would not be motivated to combine the teachings of the prior art references to arrive at the presently claimed invention. Therefore, the Applicants respectfully request that this rejection be withdrawn.

Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the obviousness-type rejection and anticipation rejection be withdrawn. The Examiner is invited to call the undersigned if

there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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By: _____
D. Peter Hochberg
Reg. No. 24,603

D. Peter Hochberg Co., L.P.A.
1940 East 6th Street, 6th Floor
Cleveland, OH 44114
(216) 771-3800